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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,446	06/20/2005	Zhiwen Zhou	Q88152	8654

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
07/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,446	ZHOU ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-6-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence Alignments*.

DETAILED ACTION

This Office action is in response to the communication filed .

Claims 1-6, 9, 13-15 are pending in the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Applicant's arguments with respect to claims 1-7, 9-12 have been considered but are moot in view of the new ground(s) of rejection set forth below.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spetz-Holmgren et al (US 2002/031521) and Merigan et al (USPN 7,129,041), the combination in view of McSwiggen et al (US 2003/0175950) and Tuschl et al (WO 02/44321).

The claims are drawn to an siRNA which is a hairpin, comprising a fragment between 19-28 bases of SEQ ID NO. 3 and its complement, and further comprising a 5' or 3' UU overhang, which siRNA targets HIV, and which siRNA is in an appropriate expression vector and which is encapsulated in a liposome.

Spetz-Holmgren et al (US 2002/031521) teach a nucleic acid fragment comprising SEQ ID NO. 3 (See Acc. No. ABL56070 of Spetz-Holmgren, and its alignment with SEQ ID NO. 3 of the instant application).

Merigan et al (USPN 7,129,041) teach a nucleic acid fragment comprising SEQ ID NO. 3 (See SEQ ID NO. 8 of Merigan et al, and its alignment with SEQ ID NO. 3 of the instant application).

The primary references do not teach siRNA which is a hairpin, comprising a fragment between 19-28 bases of SEQ ID NO. 3, and further comprising a 5' or 3' UU overhang, which siRNA targets HIV, and which siRNA is in an appropriate expression vector and which nucleic acid is encapsulated in a liposome.

McSwiggen et al (US 2003/0175950) teaches siRNA molecules between 19-23 nucleobases per strand, which siRNA molecules specifically target and inhibit the

expression of HIV, and which siRNA optionally further comprise terminal overhangs, and which sense and antisense strands are optionally joined by nucleoside or non-nucleoside residues, and which siRNA molecules are expressed in an appropriate expression vector and encapsulated in liposomes (see esp. the abstract, paragraphs 0001-2, 0010-0014, 0129-0130, 0141-0143, 0160, 0189-0194, 0196, claims 1-7, 11-13 and 26).

Tuschl et al (WO 02/44321) teach the routine design, testing and optimization of siRNA molecules for targeting and inhibiting the expression of a target gene of known sequence, which siRNA strands are optionally between 19-25 nucleobases in length, and comprise UU terminal overhangs (see esp. the abstract, pages 1-7, 44-51, claims 1-5, figures 7, and 811-23).

It would have been obvious to design and construct an siRNA molecule comprising a fragment between 19-28 bases of SEQ ID NO. 3, and further comprising a 5' or 3' UU overhang because oligonucleotides comprising fragments within this approximate size range were well known in the art to target HIV, as taught previously by Spetz-Holmgren and Merigan. One would have been motivated to design siRNAs for targeting and inhibiting HIV because McSwiggen taught the ability of siRNAs of the claimed size range for targeting and inhibiting the expression of HIV, including siRNAs with terminal overhangs, and the advantages of using siRNAs to inhibit target gene expression was well known in the art, as taught previously by McSwiggen and Tuschl. It would have been obvious to design an siRNA comprising a single molecule joining both the sense and antisense strands because this had been taught previously by

McSwiggen, and expression of a single molecule would optimize siRNA strand coupling and preclude the necessity of annealing of two distinct strands in a cell. One would have been motivated to design UU terminal overhangs for the instantly claimed siRNA molecules because the advantages of inserting UU overhangs were taught previously by Tuschl, and provide siRNA stability from degradation without detracting from the binding or inhibitory capacity of siRNA molecules. One also would have been motivated to express siRNA molecules in an appropriate expression vector because this would provide for enhanced expression of a larger concentration of siRNAs in an appropriate target cell, as taught previously by McSwiggen et al. One would have been motivated to encapsulate the instantly claimed nucleic acids within liposomes because such encapsulation was well known to enhance target cell uptake of nucleic acids, as taught previously by many in the field, including McSwiggen. One of skill in the art would have reasonably expected that the instantly claimed nucleic acids would have enhanced stability, enhanced cellular uptake and would provide for the inhibition of expression of HIV, relying on the combined teachings of Spetz-Holmgren, Merigan, McSwiggen, and Tuschl.

For these reasons, the instant invention would have been obvious to one of ordinary skill in the art at the time of filing.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

(December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE CO PIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
7-22-09

/Jane Zara/

Primary Examiner, Art Unit 1635